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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,735	01/28/2004	Mark G. Currie	14184-039001	4325
26161	7590	10/04/2006	EXAMINER	
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			TELLER, ROY R	
			ART UNIT	PAPER NUMBER

1654

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/766,735		CURRIE ET AL.	
	Examiner		Art Unit	
	Roy Teller		1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 72-89 is/are pending in the application.
- 4a) Of the above claim(s) 75-77, 79-83 and 85-89 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 72-74, 78 and 84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/04, 11/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election with traverse of elected group I, claims 72-74, 78 and 84, drawn to the purified polypeptide of SEQ ID NO: 125, in the reply filed on 7/27/06 is acknowledged. The traversal is on the ground(s) that group II, claims 75-77, drawn to the purified polypeptide of SEQ ID NO: 126, would not impose any meaningful additional search burden on the examiner. This is not found persuasive because SEQ ID NO's 125 and 126 are drawn to different chemical structures requiring different searches as indicated by their different classifications.

The requirement is still deemed proper and is therefore made FINAL.

Claims 75-77, 79-83, and 85-89 are withdrawn as being drawn to unelected subject matter.

Claims 72-74, 78 and 84 are pending.

Information Disclosure Statement

The information disclosure statements, received 12/3/04 and 11/3/05, are acknowledged. A signed copy of each is enclosed hereto.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 72-74, 78 and 84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 72-74 recited ... “ wherein Xaa is selected from Phe, Trp **and** Tyr...” . This is vague and indefinite as to the metes and bounds of SEQ ID NO: 125. The sequence listing in the instant application recites SEQ ID NO: 125 as- Xaa selected from Phe, Trp **or** Tyr. The examiner is unclear as to length of SEQ ID NO: 125, 13 or 16 amino acids. Clarification is requested.

All other claims depend directly or indirectly from the rejected claims and are, therefore, also rejected under 35 USC 112, second paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 72, 78, and 84 are rejected under 35 U.S.C. 102(b) as being anticipated by Giannella (J. of Lab. and Clin. Med., 1995, vol. 125, no. 2, pp-173-181).

The instant invention is drawn to a purified polypeptide comprising the amino acid sequence of SEQ ID NO: 125.

Giannella discloses E. coli heat stable enterotoxins, guanylin and their receptors. The structure of E. coli STh, a purified 19 amino acid peptide is shown in figure 1, page 174. This is a 92% sequence match from C(6) to C(18) of figure 1 with SEQ ID NO: 125 of the instant

invention. Applicant's claims are clearly open to other active ingredients such as peptides because of the term "comprising". "Comprising" leaves the claim open for the inclusion of unspecified ingredients even in major amounts. See MPEP 2111.03

Therefore, the reference is deemed to anticipate the instant claims above.

Conclusion

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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9/27/06

RT



Cecilia J. Tsang
Supervisory Patent Examiner
Technology Center 1600